



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1302

RIN 0970-AC90

Removal of the Vaccine Requirements for Head Start Programs

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule removes the vaccine and testing requirements included in the Interim Final Rule with Comment Period (IFC) titled, “Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs,” which the Administration for Children and Families published on November 30, 2021. Specifically, this rescission removes the requirement from the Head Start Program Performance Standards (HSPPS) that all Head Start staff, contractors whose activities involve contact with or providing direct services to children and families, and volunteers working in classrooms or directly with children are fully vaccinated for COVID-19. The associated HSPPS requirement that staff who are exempt from the vaccination requirement have “at least weekly” COVID-19 testing is also removed.

DATES: *Effective date:* This final rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Kate Troy, OHS, at HeadStart@eclkc.info or 1-866-763-6481. Telecommunications Relay Service users can first dial 7-1-1, then share the 1-866-763-6481 number with the operator.

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I. Executive Summary

(1) Purpose of the Regulatory Action

The purpose of this regulatory action is to remove the COVID-19 vaccination and testing requirements established by the Interim Final Rule with Comment Period (IFC), *Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs*, which ACF issued on November 30, 2021 (86 FR 68052), from the Head Start Program Performance Standards (HSPPS). Specifically, this final rule removes the requirement that all Head Start staff, contractors whose activities involve contact with or providing direct services to children and families, and volunteers working in classrooms or directly with children are fully vaccinated for COVID-19. Accordingly, the removal of the vaccine requirement also removes the related “at least weekly testing” requirement that staff who are granted an exemption from the vaccine requirement undergo. These requirements are no longer part of the HSPPS.

Factors that have led ACF to remove these requirements include 1) the expiration of the COVID-19 Public Health Emergency on May 11, 2023 declared by the Secretary of Health and Human Services under the Public Health Service Act and the national emergency concerning COVID-19 ended on April 10, 2023 when the President signed Public Law No. 118-3, 2) the fact that Head Start programs are required, through a final rule issued on January 6, 2023, to have an evidence-based COVID-19 mitigation policy included in their policies and procedures, and 3) comments received on the IFC (86 FR 68052).

HHS finds good cause for promulgating this final rule with an immediate effective date to promote efficient planning and ease of implementation. A delayed effective date could harm Head Start programs' ability to plan for the upcoming program year, as many Head Start programs use the summer months to recruit and hire staff. Any confusion or uncertainty created by the continued presence of the COVID-19 vaccination and testing requirements within the HSPPS could prevent programs from hiring otherwise qualified staff during the typical hiring season. Further, delays in hiring staff for the upcoming program year ultimately limits the number of children and families served by Head Start. This outcome is contrary to the public interest and subverts the intended purpose of this regulatory action.

(2) Summary of Costs and Benefits

This final rule removes the COVID-19 vaccination and testing requirements established on November 30, 2021 through an Interim Final Rule with Comment (IFC), "Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs."¹ In this analysis, we evaluate the impacts of the final rule in comparison to a primary analytic baseline scenario in which these IFC requirements continue over the time horizon of the analysis. We also discuss the impacts in comparison to an alternative baseline scenario of no vaccination and testing requirements.

The final rule will result in fewer COVID-19 tests performed under the testing requirement for individuals granted an exemption from the vaccine requirement. This analysis estimates \$16.8 million in cost savings associated with fewer tests performed. The final rule will also result in reduced vaccine uptake among some individuals hired by Head Start programs over the time horizon of this analysis, who would become fully vaccinated under the IFC but who will not become fully vaccinated without the vaccination requirement. We estimate \$1.7 million in cost savings associated with fewer new hires becoming fully vaccinated. We also identify foregone benefits in the form of reduced COVID-19 mortality and morbidity risks associated

¹ 86 FR 68052

with vaccination. We monetize these mortality risks using a value per statistic life approach and report a primary value of these disbenefits of about \$0.7 million. Over a one-year time horizon, we estimate that this final rule will result in about \$18.5 million in total cost savings. Subtracting disbenefits from the cost savings, we conclude that this final rule will result in net benefits of about \$17.8 million.

These estimates are reported in 2022 dollars and do not depend on the choice of 3% or 7% discount rate. As discussed in greater detail in the full analysis, we acknowledge some uncertainty in these estimates, including that some Head Start programs likely adopted evidence-based COVID-19 mitigation policies that include testing or vaccination strategies.

We have developed a comprehensive regulatory impact analysis that assesses the impacts of the final rule. The full analysis of economic impacts is available Section VIII of this document.

II. Background

Since its inception in 1965, Head Start has been a leader in supporting children from low-income families in reaching kindergarten healthy and ready to thrive in school and life. The program was founded on research showing that health and wellbeing are pre-requisites to maximum learning and improved short- and long-term outcomes. In fact, OHS identifies health as the foundation of school readiness.

The Head Start Program Performance Standards (HSPPS) require programs to comply with state immunization enrollment and attendance requirements and to work with families to ensure children who are behind on immunizations or other care get on a schedule to catch up (45 CFR 1302.15(e) and 1302.42(b)(1)). Additionally, education, family service, nutrition, and health staff help children learn healthy habits, monitor each child's growth and development, and help parents access needed health care.

It is vitally important that the Head Start program itself is safe for all children, families, and staff. For this reason, the HSPPS specify that the program must ensure Head Start staff do

not pose a significant risk of communicable disease (45 CFR 1302.93(a)). Ensuring that children and families can benefit from program services as safely as possible is OHS' highest priority. While this is always important, the COVID-19 pandemic highlighted the need to ensure staff are as protected as possible so that young children are also protected. At the time of the IFC's publication, November 30, 2021, the COVID-19 vaccine was the most effective risk reduction strategy available to avoid severe illness, hospitalization, and death, as well as the most important measure for reducing risk for SARS-CoV-2 transmission² for the predominant variants of SARS-CoV-2. Data at the time suggested fully vaccinated staff were at much lower risk of infection and therefore, posed lower transmission risk to the young unvaccinated children in their care.³ Young children who get the virus can also spread it to others in their homes and communities. Ensuring Head Start staff were fully vaccinated thus had the ancillary benefit of significantly reducing the possibility of the program playing an unwitting part in community spread of SARS-CoV-2.

ACF published an Interim Final Rule with Comment Period (IFC) in the **Federal Register** on November 30, 2021 (86 FR 68052). ACF issued the IFC on the basis of its authority in Section 641A of the Head Start Act, which allows the Secretary to “modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs,” including “administrative and financial management standards,” “standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) for such agencies, and programs,” and “such other standards as the Secretary finds to be appropriate,” 42 U.S.C. § 9836a(a)(1)(C),(D), and (E). In developing these modifications, the Secretary included relevant considerations pursuant to section 641A(a)(2) of the Head Start Act, 42 U.S.C. 9836a(a)(2)⁴. The Secretary consulted with experts in child health, including

² Centers for Disease Control and Prevention. “Science Brief: COVID Vaccines and Vaccination.” <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

³ CDC. “Overview of Testing for SARS-CoV-2 (COVID-19)” October 22, 2021. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>

⁴ Not all the listed considerations are included because they are only relevant to certain standards, such as curriculum.

pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA^{5,6,7,8}. The Secretary considered OHS's past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies. Challenges considered included the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures. Based on all these factors, the Secretary found it necessary and appropriate to set health and safety standards for the condition of Head Start facilities that help to reduce transmission of the SARS-CoV-2 and to help avoid severe illness, hospitalization, and death among program participants.

As of Jan. 1, 2022,^{9,10} following a decision by the United States District Court for the Northern District of Texas and the Western District of Louisiana, implementation and enforcement of the IFC was preliminarily enjoined in the following 25 states: Alabama, Alaska, Arizona, Arkansas, Florida, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. Head Start, Early Head Start, and Early Head Start-Child Care Partnership grant recipients in those 25 states were not required to comply with the IFC pending future developments in the litigation. The IFC remained in effect in all other states, the District of Columbia, and U.S. territories.

⁵ CDC. "Science Brief: COVID Vaccines and Vaccination." <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

⁶ CDC. "Delta Variant: What We Know About the Science." August 26, 2021. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html>

⁷ Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0-17 Years—United States, August 2020–August 2021 | MMWR.

⁸ <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status> MMWR Morb Mortal Wkly Rep 2021;70:1255-1260. DOI: <http://dx.doi.org/10.15585/mmwr.mm7036e2>.

⁹ *Texas et al. v. Becerra, et al.*, No. 21-cv-00300, 2021 WL 6198109 (N.D. Tex. Dec. 31, 2021)

¹⁰ *Louisiana, et al. v. Becerra, et al.*, 21-cv-04370, 2022 WL 16571 (Jan. 1, 2022 W.D. La.)

As of the date of publication of the IFC, children under the age of 5 were not eligible for the COVID-19 vaccine. On June 17, 2022, the U.S. Food and Drug Administration (FDA) authorized the emergency use of the Moderna and Pfizer-BioNTech COVID-19 vaccines to include children 6 months through 5 years of age. While becoming fully vaccinated takes time, and uptake for this cohort has been slow, this remains a critical milestone in the pandemic response. Because vaccinations are now available to children 6 months through 5 years of age, Head Start children are now less vulnerable to the effects of COVID-19. COVID-19 vaccines continue to protect against severe disease, hospitalization, and death in children and adolescents.

On March 31, 2023, the United States District Court for the Northern District of Texas vacated the Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs, 86 Fed. Reg. 68052 (Nov. 30, 2021) (the “Interim Final Rule” or “IFC”). That decision took effect on April 7, 2023. Because of this ruling, as of April 7, there is no longer a Head Start requirement for vaccination and testing for Head Start, Early Head Start, and Early Head Start-Child Care Partnership grant recipients in all states, tribes, and territories.

On April 10, 2023, President Biden signed legislation that ended the COVID-19 national emergency declared by the President under the National Emergencies Act. On May 11, 2023, the COVID-19 public health emergency expired.

III. Rationale for the Rescission of the Vaccine Requirements

In enacting the IFC, OHS pointed to the substantial evidence at the time of the efficacy of COVID-19 vaccines and the use of masks in reducing transmission of SARS-CoV-2, offering both personal and communal benefits. The COVID-19 vaccine was the most effective risk reduction strategy available to avoid severe illness, hospitalization, and death, as well as the most

important measure for reducing risk for SARS-CoV-2 transmission¹¹ for the predominant variants of SARS-CoV-2.

The rationale for the removal of the vaccination requirements through this Final Rule is threefold. First, the Public Health Emergency (PHE) declaration came to an end on May 11, 2023 and the national emergency concerning COVID-19 ended on April 10, 2023 when the President signed Public Law No. 118-3. While vaccination remains one of the most important tools in advancing the health and safety of individuals, this phase of the response is different than it was when ACF required vaccination of Head Start staff.^{12,13,14,15,16} As of May 1, 2023, COVID-19 deaths have declined by 97%, and hospitalizations are down nearly 81%, since November 2021.¹⁷ Globally, COVID-19 deaths are at their lowest levels since the start of the pandemic.¹⁸ Additionally, due to the nature of a prolonged pandemic, the majority of Americans have experienced multiple immunization effects—natural and inoculative. Data indicate infection- and vaccine-induced population immunity in the United States was 95% by December 2021.¹⁹ To mitigate the consequences of the pandemic, approximately 675 million COVID-19 vaccine doses were administered, including 55 million updated (bivalent) booster doses.²⁰

¹¹ CDC. “Science Brief: Vaccines and Vaccination.” <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

¹² Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021 | MMWR

¹³ <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status> MMWR Morb Mortal Wkly Rep 2021;70:1255–1260. DOI: <http://dx.doi.org/10.15585/mmwr.mm7036e2>

¹⁴ <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination>

¹⁵ Johnson AG, Amin AB, Ali AR, et al. COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence — 25 U.S. Jurisdictions, April 4–December 25, 2021. MMWR Morb Mortal Wkly Rep 2022;71:132–138. DOI: <http://dx.doi.org/10.15585/mmwr.mm7104e2>external icon.

¹⁶ Centers for Disease Control and Prevention. “Science Brief: Vaccines and Vaccination.” <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

¹⁷ Centers for Disease Control and Prevention. COVID Data Tracker. Atlanta, GA: US Department of Health and Human Services, CDC; 2023, May 26. <https://covid.cdc.gov/covid-data-tracker>

¹⁸ <https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/01/the-biden-administration-will-end-covid-19-vaccination-requirements-for-federal-employees-contractors-international-travelers-head-start-educators-and-cms-certified-facilities/>

¹⁹ Jones JM, Opsomer JD, Stone M, et al. Updated US infection- and vaccine-induced SARS-CoV-2 seroprevalence estimates based on blood donations, July 2020–December 2021. JAMA 2022;328:298–301. <https://doi.org/10.1001/jama.2022.9745> PMID:35696249

²⁰ CDC. COVID-19 data review: update on COVID-19–related mortality. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. Accessed April 14, 2023. <https://www.cdc.gov/coronavirus/2019-ncov/science/data-review/index.html>

Relatedly, and particularly impactful for the population Head Start programs serve, is the availability and uptake of the COVID-19 vaccine for young children and its inclusion in the CDC's Immunization Schedules.²¹ Note that there is waning immunity following vaccination, however, immunization efforts are improving due to greater access to vaccination and more widespread natural immunity. Though COVID-19 is still an ongoing public health issue, it is no longer a societal emergency as it was at the onset of the pandemic and no longer necessitates the same level of federal response. Similarly, the change in pandemic conditions reflected in the termination of the national emergency and public health emergency likewise would make it appropriate to rescind the masking requirement if that requirement were still in effect.

Second, on January 6, 2023, ACF issued a Final Rule (88 FR 993) requiring Head Start grant recipients to have an evidence-based COVID-19 mitigation policy, which considers multiple mitigation strategies such as vaccination, masking, ventilation, testing, and staying home when sick that can be scaled up or down as COVID-19 conditions necessitate.

ACF strongly recommends that Head Start programs use vaccines and tests as part of their mitigation policy to reduce the spread of COVID-19 and reduce the likelihood of mortality or morbidity from infection. Head Start programs may choose to include their own requirements to support vaccination efforts, including for example, requiring staff remain up to date on COVID-19 vaccines, sharing information on COVID-19 vaccination with staff and families, and/or partnering with local agencies to increase vaccination access. With this new requirement of an evidence-based COVID-19 mitigation policy in place, Head Start grant recipients are better positioned to respond to future surges of SARS-CoV-2.

Finally, as discussed in detail below, ACF considered public comments on the IFC when making the decision to rescind the vaccine and testing requirements.

IV. Overview of Public Comments on the Interim Final Rule with Comment Period

²¹ CDC. "Child and Adolescent Immunization Schedule by Age." Recommendations for Ages 18 Year and Younger, United States, 2023. Available at: <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

The comment period for the IFC was open for 30 days and closed on December 30, 2021. OHS received 2,794 comments, of which 2,690 were unique submissions. Most comments came from individuals, including Head Start directors, other Head Start staff members, Members of Congress, and parents. A smaller subset of comments came from associations on behalf of their membership.

We discussed many of these comments in the Final Rule issued on January 6, 2023, including global comments pertaining to the perceived burden of the vaccine and masking requirements, the reported challenges to enrollment, the implementation timeline, and the open-ended, indefinite nature of the requirements. In Part V. Public Comments Analysis of this Final Rule, we focus on comments that are specific to the vaccination requirement, and the associated “at least weekly” testing requirement for those who are granted an exemption to the vaccination requirement. These comments account for approximately one-quarter of the comments received on the IFC.

V. Public Comments Analysis

In this section, we provide a summary of the comments we received on the IFC related to the vaccine and testing requirements outlined in Section 1302.93(a)(1)-(2) and 1302.94(a)(1)-(2).

Comment: Commenters raised concerns with the lack of the termination date for the vaccine requirements. In the IFC, ACF invited comment on the decision to leave an undetermined end date or set a finite end date, such as 6 months from the effective date of the rule. Programs reported concerns that the indefinite nature of the requirement impedes their ability to update their internal policies, inform staff of expectations, update parents and families, budget for next year and outline expectations for prospective staff and families. Several commenters noted that public health emergency declarations come to an end and objected that the vaccine and testing requirements were “made permanent” by including them in the Head Start Program Performance Standards.

Response: ACF is removing the vaccine requirement in this final rule, which means Head Start programs are no longer determining which staff are exempt from the vaccine requirement and requiring “at least weekly” testing for those granted an exemption unless their program opts to include such requirements under its COVID mitigation policy.

Comment: Commentors raised concerns about providers paid partially with Head Start funds who are subject to the Head Start vaccination requirement but are not required by their employer to be vaccinated. There is concern that school districts and other partners that do not have a masking or vaccination requirement will opt out of partnerships and consider withdrawing contracts. This would result in the loss of services to children and families – a loss in classroom space, transportation options, etc. Similarly, there was also concern that children in Head Start programs situated within partnerships would be unfairly singled out and/or discriminated against by other children in the setting (who are not subject to the mask requirement).

Response: OHS understands this concern and appreciates the comments from those who described the partnerships Head Start programs have established and sustained in their communities over many years. OHS is removing the national vaccine requirement in this final rule and, in doing so, has addressed the concerns from these commenters.

As noted, ACF issued a Final Rule, Mitigating the Spread of COVID-19 in Head Start Programs, on January 6, 2023, that requires Head Start programs to have an evidence-based COVID-19 mitigation policy developed in consultation with the program's Health Services Advisory Committee (HSAC). ACF recommends that Head Start programs use vaccines and tests as part of their mitigation policy to reduce the spread of COVID-19 and reduce the likelihood of mortality or morbidity from infection. Head Start programs may choose to include their own requirements to support vaccination efforts, including for example, requiring staff remain up to date on COVID–19 vaccination, sharing information on COVID–19 vaccination with staff and families, and/or partnering with local agencies to increase vaccination access.

Comment: Commentors were concerned about the impact of these requirements on access to special education services under Individuals with Disabilities Education Act (IDEA).

Comments expressed concern that early intervention providers and other professionals providing special education and related services to enrolled children through Part B and C of IDEA, some of whom may not be required to be vaccinated by their employers, are required to be vaccinated under the IFC. There were concerns that there will be a reduction in children's access to early identification, early intervention, and special education services, which could potentially result in children not receiving services to which they are legally entitled under IDEA if Local Education Agencies (LEA) do not have similar vaccination requirements.

Response: OHS has removed the national vaccine requirement in this final rule and therefore, addressed these concerns. Though special education, early intervention, health service providers and other related service providers (e.g., IDEA Part B/C providers) are neither staff of Head Start programs nor contractors and were never included in the vaccination requirement, the removal of the vaccine requirement should address any concerns about the reduction in services or perceived barriers in services for children in need of early intervention, special education, or related services. Given the critical nature of the services provided through these partnerships, to further address the concerns raised, OHS released an FAQ that made clear these providers were not included in the requirement. Additionally, in partnership with the U.S. Department of Education's Office of Special Education Programs, OHS authored a Dear Colleague Letter and guidance document stating that state and local educational agencies and Head Start programs have responsibilities for implementing IDEA to ensure that children with disabilities enrolled in Head Start programs receive a free appropriate public education in the least restrictive environment.

Comment: Commentors were concerned that those given an exemption were being discriminated against because they were being singled out for testing. Some suggested requiring testing for all, regardless of vaccination status. Others encouraged an opt-out option for all staff

with the hopes of fewer staff leaving for employment elsewhere. Conversely, commentors were concerned with the burden imposed on grantees to implement and track weekly testing, especially in rural areas with limited access to tests.

Response: OHS has removed the vaccination requirement and consequently the “at least weekly” testing requirement for those staff exempt from the vaccine requirement. Though OHS did not receive any reports of widespread difficulty accessing tests and/or tracking of test results or indication of discrimination on the basis of being singled out for testing, the rescission of this requirement in the final rule should also address any remaining concerns with regard to testing.

Comment: Some commentors reported that Head Start staff do not have to provide their COVID-19 vaccination status or proof of vaccination status because that information is protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Other commentors raised general concerns that the vaccination requirements should not be mandated by their place of employment. Commentors felt that medical requirements are a violation of employee rights and that vaccines should be a personal choice.

Response: In accordance with HHS guidance, HIPAA does not prohibit any person from asking whether an individual has received a particular vaccine, including COVID-19 vaccines. Since 1998, OHS has required that programs ensure staff do not pose a significant risk of communicable disease (45 CFR 1302.93(a)). At the time of the IFC’s publication, the COVID-19 vaccine was an important requirement that reduced transmission of SARS-COV-2. While OHS disagrees with these comments, OHS is no longer requiring all Head Start staff, contractors whose activities involve contact with or providing direct services to children and families, and volunteers working in classrooms or directly with children to be vaccinated for COVID-19.

VII. Regulatory Process Matters

Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires federal agencies to determine whether a policy or regulation may negatively affect

family well-being. If the agency determines a policy or regulation negatively affects family well-being, then the agency must prepare an impact assessment addressing seven criteria specified in the law. ACF believes it is not necessary to prepare a family policymaking assessment, see Public Law 105-277, because the action it takes in this final rule will not have any impact on the autonomy or integrity of the family as an institution.

Federalism Assessment Executive Order 13132

Executive Order 13132 requires federal agencies to consult with state and local government officials if they develop regulatory policies with federalism implications. Federalism is rooted in the belief that issues that are not national in scope or significance are most appropriately addressed by the level of government close to the people. This rule will not have substantial direct impact on the states, on the relationship between the federal government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA) allows Congress to review certain rules issued by federal agencies before the rules take effect. *See* 5 U.S.C. 801(a). The CRA defines such a rule as one that has resulted, or is likely to result, in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. *See* 5 U.S.C. 804(2). The Office of Information and Regulatory Affairs in the Office of

Management and Budget has determined that this action does not fall within the scope of 5 U.S.C. 804(2).

Paperwork Reduction Act of 1995

The Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501 et seq., minimizes government-imposed burden on the public. In keeping with the notion that government information is a valuable asset, it also is intended to improve the practical utility, quality, and clarity of information collected, maintained, and disclosed.

The PRA requires that agencies obtain OMB approval, which includes issuing an OMB number and expiration date, before requesting most types of information from the public. Regulations at 5 CFR part 1320 implemented the provisions of the PRA and § 1320.3 of this part defines a “collection of information,” “information,” and “burden.” PRA defines “information” as any statement or estimate of fact or opinion, regardless of form or format, whether numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic, or other media (5 CFR 1320.3(h)). This includes requests for information to be sent to the government, such as forms, written reports and surveys, recordkeeping requirements, and third-party or public disclosures (5 CFR 1320.3(c)). “Burden” means the total time, effort, or financial resources expended by persons to collect, maintain, or disclose information.

The existing OMB Control Number for this information collection request (ICR) is 0970-0583. This final rule will remove the majority of reporting requirements approved under this OMB Control Number. The only recordkeeping requirement that will remain is the recordkeeping requirement that grant recipients update their program policies and procedures with the evidence-based COVID-19 mitigation policy, which was required in the final rule published on January 6, 2023 (88 FR 993). There are no new recordkeeping activities associated with this final rule.

VIII. Regulatory Impact Analysis

I. Introduction and Summary

A. Introduction

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is a significant regulatory action as defined by Executive Order 12866. Thus, this rule has been reviewed by the Office of Information and Regulatory Affairs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the impacts to small entities attributable to the final rule are cost savings, this analysis concludes, and the Secretary certifies, that the final rule will not have a significant economic impact on a substantial number of small entities. These impacts are discussed in detail in the Final Small Entity Analysis.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in expenditures in any year that meet or exceed this amount.

B. Summary of Benefits and Costs

This final rule removes the COVID-19 vaccination and testing requirements established on November 30, 2021 through an Interim Final Rule with Comment (IFC), “Vaccine and Mask

Requirements To Mitigate the Spread of COVID-19 in Head Start Programs.”²² In this analysis, we evaluate the impacts of the final rule in comparison to a primary analytic baseline scenario in which these IFC requirements continue over the time horizon of the analysis. We also discuss the impacts in comparison to an alternative baseline scenario of no vaccination and testing requirements.

The final rule will result in fewer COVID-19 tests performed under the testing requirement for individuals granted an exemption from the vaccine requirement. This analysis estimates \$16.8 million in cost savings associated with fewer tests performed. The final rule will also result in reduced vaccine uptake among some individuals hired by Head Start programs over the time horizon of this analysis, who would become fully vaccinated under the IFC but who will not become fully vaccinated without the vaccination requirement. We estimate \$1.7 million in cost savings associated with fewer new hires becoming fully vaccinated. We also identify foregone benefits in the form of reduced COVID-19 mortality and morbidity risks associated with vaccination. We monetize these mortality risks using a value per statistic life approach and report a primary value of these disbenefits of about \$0.7 million. Over a one-year time horizon, we estimate that this final rule will result in about \$18.5 million in total cost savings. Subtracting disbenefits from the cost savings, we conclude that this final rule will result in net benefits of about \$17.8 million. These estimates are reported in 2022 dollars and do not depend on the choice of 3% or 7% discount rate. As discussed in greater detail in the full analysis, we acknowledge some uncertainty in these estimates, including that some Head Start programs likely adopted evidence-based COVID-19 mitigation policies that include testing or vaccination strategies.

²² 86 FR 68052

II. Analysis of the Final Rule

A. Background and Baselines

On November 30, 2021, ACF published an interim final rule with comment period on “Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs” (IFC).²³ The IFC added provisions to the Head Start Program Performance Standards to impose three requirements:²⁴

1. Universal masking, with some noted exceptions, for all individuals two years of age and older when there are two or more individuals in a vehicle owned, leased, or arranged by the Head Start program; when they are indoors in a setting where Head Start services are provided; and, for those not fully vaccinated, outdoors in crowded settings or during activities that involve close contact with other people.

2. Vaccination for COVID-19 for Head Start program staff, certain contractors and volunteers by January 31, 2022.

3. For those granted an exemption to the requirement specified in (2), at least weekly testing for current SARS-CoV-2 infection.

On January 6, 2023, ACF published a final rule on “Mitigating the Spread of COVID-19 in Head Start Programs.”²⁵ That final rule modified the IFC to remove the requirement for universal masking for all individuals ages 2 and older, and to require that Head Start programs have an evidence-based COVID-19 mitigation policy, developed in consultation with their Health Services Advisory Committee. It did not address the vaccination and testing requirements of the IFC.

In our analysis of this final rule, we adopt a baseline scenario of the requirements of the November 30, 2021 IFC, as modified by the January 6, 2023 final rule. This choice of baseline includes ongoing impacts associated with the testing requirements. It also includes impacts

²³ Ibid

²⁴ Ibid

²⁵ 88 FR 993

associated with the vaccination requirement; however, these impacts are limited to individuals who will be newly hired over the time horizon of the analysis, since the effective date of the vaccination requirement for existing staff has passed. As discussed in greater detail in the Preamble, the requirements addressed in this final rule are not in effect as a result of a ruling by the United States District Court for the Northern District of Texas. Under an alternative baseline that accounts for this ruling or that compares against a hypothetical future in which the IFC had never been issued, the final rule would result in no benefits or costs.

B. Cost Savings Associated with the Testing Requirement

To estimate the cost savings of removing the testing requirement, we first estimate the number of tests required, and the costs of testing, under our baseline scenario. We follow the general approach of the IFC RIA, with several revisions to the assumptions identified in that analysis. First, the IFC RIA's cost estimates covered 273,000 Head Start staff, consistent with data available at the time that analysis was published and the time horizon it covered. In this RIA, we adopt a lower estimate of 245,700 Head Start staff covered under the baseline scenario. This estimate is consistent with more recent data from Head Start programs, and projections of a 10% reduction in the Head Start workforce over the time horizon of this RIA compared to the period covered in the IFC RIA.²⁶ Second, the IFC RIA assumed that 5% of Head Start staff would receive an exemption from the vaccine requirement. This likely underestimated the share of staff receiving an exemption, so we increase this estimate to 8.5%. Third, the IFC RIA presented data that 83% Head Start centers were operating in-person or hybrid. Based on that data, the IFC RIA reduced the number of staff requiring testing by 17%, since screening testing would not impact staff at virtual/remote or closed centers. Applying updated data, the RIA for

²⁶ Note it is difficult to determine what share of recruitment and retainment challenges are attributable to this requirement as compared to other causes. ACF is aware that compensation has significantly affected the early childhood workforce shortage and is the number one reason for Head Start staff attrition. Research with the broader early childhood education (ECE) field indicates higher compensation for ECE professionals can improve employment stability and reduce turn-over (and vice versa, with lower wages linked to high turn-over). Additionally, we have no evidence that the workforce challenges differed between Head Start programs required to implement the IFC and those that were not (as a result of litigation that enjoined 25 states).

the January 6, 2023 final rule adopted an estimate of 94% of centers operating in-person or hybrid. In this analysis, we assume that 100% of centers operate in-person or hybrid over the time horizon of the analysis.

Combining these assumptions, we estimate that 24,570 staff that are not fully vaccinated would be tested under the baseline scenario. We maintain the assumption of the IFC RIA that each test costs \$10. We identify a second cost of time spent testing, adopting an assumption that each test takes 15 minutes to perform. Using a value of time of \$29.82 per hour,²⁷ this is \$7.46 in time costs per person tested, or \$17.46 in total costs per person tested. Across 24,570 staff tested weekly, this is a weekly cost of testing of \$428,869.

Thus, we estimate that the final rule, which removes the testing requirement, would result in \$428,869 in weekly cost savings. For the purposes of this analysis, we assume that Head Start programs operate in-person, on average, 9 months per year, or about 39 weeks per year.

Multiplying the weekly cost savings by the number of weeks results in \$16.8 million in cost savings over one calendar year. We acknowledge several sources of uncertainty in this estimate, each of which may contribute to overestimating these cost savings. First, some Head Start programs likely adopted evidence-based COVID-19 mitigation policies that include testing, thus reducing the impact of this final rule on testing. Second, some individuals that will no longer be required to test weekly will continue to test routinely, or on an ad hoc basis, unrelated to Head Start policies. Third, our baseline scenario assumes ‘full compliance’ with the IFC, which may overstate the quantity of tests that would be performed under the IFC, even absent the ruling by the United States District Court for the Northern District of Texas.

C. Cost Savings Associated with Removing the Vaccination Requirement

²⁷ According to the U.S. Bureau of Labor Statistics, the hourly median wage for Preschool and Kindergarten Teachers in the Child Day Care Services industry is \$14.91 per hour. We assume that benefits plus indirect costs equal approximately 100 percent of pre-tax wages, and adjust this hourly rate by multiplying by two, for a fully loaded hourly wage rate of \$29.82. U.S. Bureau of Labor Statistics. Occupational Employment and Wage Statistics, May 2022 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 624400 - Child Day Care Services. Median hourly wage. https://www.bls.gov/oes/current/naics4_624400.htm.

To estimate the cost savings of removing the vaccination requirement, we first estimate the number of individuals who would be newly subject to the vaccination requirement under the baseline scenario over the time horizon of this analysis. Specifically, we estimate the number of individuals who would be hired under the baseline scenario that are not fully vaccinated. To generate this estimate, we adopt an assumption that Head Start programs turnover and hire about 10% of teachers and staff every year, or 24,570 new hires per year. We assume that 20.9% of these new hires are not fully vaccinated, which is consistent with data as of May 10, 2023 that 79.1% of the U.S. population ≥ 18 years of age have completed a primary series.²⁸ Thus, over the time horizon of our analysis, we estimate that 5,135 new hires would be subject to the vaccination requirement. Consistent with our approach to estimating testing, we assume that 8.5% of these new hires would receive an exemption from the vaccination requirement. Combining these assumptions, we estimate 4,699 individuals would become fully vaccinated under the baseline scenario.

To monetize the costs associated with the vaccination requirement, we follow the general approach of the IFC RIA, with several revisions to the assumptions identified in that analysis. We retain the IFC RIA's estimates of \$80 per person to account for two vaccine doses and the costs of administering those doses. The IFC RIA also included an estimate of 2 hours as the time necessary to receive one COVID-19 vaccine dose, which that analysis describes as intending "to be inclusive of scheduling time; commuting time; time receiving a vaccine dose; waiting time, including after receiving a vaccine dose to watch for any reactions; and recovery time." For this analysis, we identify an additional cost associated with adverse reactions, adopting an assumption of 5.76 hours in time losses across two doses from a broader study of U.S. employer COVID-19 vaccine mandates,²⁹ or 2.88 hours per dose. These assumptions sum to 4.88 hours in time costs per dose, or 9.76 hours in time costs for two doses. We again adopt a value of time of

²⁸ <https://covid.cdc.gov/covid-data-tracker/>. Accessed May 17, 2023.

²⁹ Ferranna M, Robinson LA, Cadarette D, Eber MR, Bloom DE. 2023. "The benefits and costs of U.S. employer COVID-19 vaccine mandates." *Risk Analysis*. Published online January 17, 2023. doi:10.1111/risa.14090.

\$29.82 per hour, for \$291.04 in time costs per individual across two doses. Combined with the costs of the vaccine doses and the costs of administering doses, this is \$371.04 per individual. Across all 4,699 individuals who would become fully vaccinated under the baseline scenario, this is about \$1.7 million in costs associated with the vaccine requirement.

Thus, we estimate that the final rule, which removes the vaccination requirement, would result in about \$1.7 million in cost savings over one calendar year. We acknowledge several sources of uncertainty in this estimate. First, some Head Start programs likely adopted evidence-based COVID-19 mitigation policies that include vaccination, thus reducing the impact of this final rule on vaccination. Second, as noted in the IFC RIA, absent the IFC, Head Start teachers were more likely to be fully vaccinated than the general adult population. If individuals hired over the time horizon of this analysis are similarly more likely to be fully vaccinated than the general adult population, this would also reduce the impact of the final rule on vaccination.

D. Foregone Benefits Associated with the Final Rule

To estimate the forgone benefits associated with removing the vaccination requirement, we follow a simplified version of the approach used in the IFC RIA to estimate the health benefits from reductions in COVID-19 mortality attributable to the IFC. In that analysis, we generated forecasts of COVID-19 outcomes for a baseline scenario and an IFC scenario that were built on projections published by the Institute for Health Metrics and Evaluation (IHME). IHME has paused its COVID-19 modeling, and we have not identified a comparable replacement. For the purposes of identifying the magnitude of the forgone benefits from reduced vaccine uptake under the final rule, we consider a simpler model that adopts a static forecast of observed weekly death rates that vary by vaccine status.

CDC data indicate that, at the time the IFC was issued, the weekly death rate among unvaccinated adults was 18.25 deaths per 100,000 people; and for adults who were vaccinated without an updated booster, 1.02 weekly deaths per 100,000 people.³⁰ At the time this analysis

³⁰ <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>. Weekly death rates from November 28, 2021.

was prepared, the most recent data readily available indicate that the weekly death rate among unvaccinated adults was 1.07 per 100,000 people; and for adults who were vaccinated without an updated booster, 0.21 weekly deaths per 100,000 people.³¹ These weekly death rates include adults of all ages, and are largely driven by deaths among people 65 and older, which represent only a small fraction of the Head Start workforce. Since the impacts we are studying accrue to new hires, we focus on weekly death rates for adults between the ages of 30 and 49. For this age group, the weekly death rate among unvaccinated adults was 0.07 deaths per 100,000 people; and for adults who were vaccinated without an updated booster, 0.03 deaths per 100,000 people.

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To apply these estimates, we add assumptions such that the 4,699 individuals who would become fully vaccinated under the baseline scenario will be hired uniformly over the one-year time horizon and that they would be fully vaccinated for exactly half of the year. Thus, assuming weekly death rates remain constant, we would expect about 0.12 deaths among new hires over one year.³³ Under the final rule, these individuals would not become fully vaccinated, and we would expect about 0.17 deaths among new hires over one year.³⁴ Thus, we estimate that removing the vaccination requirement would result in mortality risk increases equal to 0.05 statistical lives. We monetize these mortality risk increases associated with lower vaccine uptake using a value per statistical life of \$12.4 million³⁵ and report an estimate of forgone benefits of about \$0.61 million.³⁶

The IFC RIA also contained estimates of morbidity risk reductions associated with the vaccine requirement. As with the mortality estimates, these outcome forecasts were built on

³¹ <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>. Weekly death rates from February 26, 2023.

³² <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>. Weekly death rates from February 26, 2023.

³³ $(0.07+0.03)/2/100,000 * 4,699 * 52 \approx 0.12$.

³⁴ $0.07/100,000 * 4,699 * 52 \approx 0.17$.

³⁵ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2021. "Updating Value per Statistical Life (VSL) Estimates for Inflation and Changes in Real Income." <https://aspe.hhs.gov/reports/updated-vsl-estimates>.

³⁶ As a sensitivity analysis, we adopt a range of VSL estimates between \$5.8 million and \$18.9 million to report a range of estimates for the forgone benefits of between \$0.3 million and \$0.9 million.

projections published by IHME. Lacking comparable projections, we produce an estimate of these forgone benefits by referencing the ratio of the total value of health benefits to the value of mortality benefits estimated in the IFC RIA. Table 25 in the IFC RIA reports a central estimate of the total value of risk reductions of \$236.8 million, and \$213.4 million as the central estimate of the mortality risk reductions. In that analysis, the total value of the health benefits is about 11% higher than the value of the mortality benefits alone. Thus, in this simplified analysis, we report foregone total benefits associated with removing the vaccination requirement of about \$0.67 million, which is about 11% larger than the \$0.61 million in mortality benefits estimated above.

We acknowledge several sources of uncertainty in addition to those identified in the previous section. First, the source data on weekly death rates are not adjusted for time since vaccination, which could result in the population estimates of the weekly death rate for vaccinated adults overestimating the weekly death rate for newly vaccinated individuals. If this is the case, then our foregone benefit estimates may be underestimated, all else equal. Second, the relative risk of COVID-19 mortality and morbidity by vaccination status has varied over time and by variant. Moreover, the estimates of the relative risk of COVID-19 mortality by vaccination status used in this analysis serve as a proxy for the effects of vaccination. There may be other factors correlated with vaccination status that also affect mortality and morbidity. Consequently, our approach may overestimate or underestimate the incremental effects of vaccination, which would pass through to our estimates of the forgone benefits of the final rule. Third, COVID-19 deaths and cases have varied over time.

III. Final Small Entity Analysis

We have examined the economic implications of this Final Rule as required by the Regulatory Flexibility Act. This analysis, as well as other sections in this Regulatory Impact Analysis, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The U.S. Small Business Administration (SBA) maintains a Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS).³⁷ We replicate the SBA's description of this table:

This table lists small business size standards matched to industries described in the North American Industry Classification System (NAICS), as modified by the Office of Management and Budget, effective January 1, 2022.

The size standards are for the most part expressed in either millions of dollars (those preceded by "\$") or number of employees (those without the "\$"). A size standard is the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm. How to calculate average annual receipts and average employment of a firm can be found in 13 CFR 121.104 and 13 CFR 121.106, respectively.

This final rule will impact small entities in NAICS category 624410, Child Care Services, which has a size standard of \$9.5 million dollars. We assume that most Head Start programs, if not all, are below this threshold and are considered small entities.

B. Description of the Impacts of the Rule on Small Entities

Compared to the baseline scenario, this final rule will result in cost savings for Head Start programs. We estimate that the incremental impact of the final rule is about \$18.5 million in net cost savings, most of which will accrue to Head Start programs. Across 20,717 centers, we estimate that these cost savings will average \$894 in cost savings per center. This analysis concludes that the final rule is not likely to result in a significant impact on a substantial number of small entities.

IX. Tribal Consultation Statement

ACF conducts an average of five tribal consultations each year for tribes operating Head Start and Early Head Start. The consultations are held in four geographic areas across the country: Southwest, Northwest, Midwest (Northern and Southern), and East. The consultations are often held in conjunction with other tribal meetings or conferences, to ensure the opportunity

³⁷ U.S. Small Business Administration (2023). "Table of Size Standards." March 17, 2023 <https://www.sba.gov/document/support--table-size-standards>.

for most of the 150 tribes that operate Head Start and Early Head Start programs to attend and voice their concerns regarding service delivery. We complete a report after each consultation, and then we compile a final report that summarizes the consultations. We submit the report to the Secretary of Health and Human Services (the Secretary) at the end of the year.

Although this rule does not have implications specific to AIAN programs, OHS will continue to collaborate with Tribes on all matters related to the Head Start Program Performance Standards.

January Contreras, Assistant Secretary of the Administration for Children and Families, approved this document on May 8, 2023.

List of Subjects in 45 CFR Part 1302

COVID-19, Evidence-based COVID-19 mitigation policy, Education of disadvantaged, Grant programs—social programs, Head Start, Health care, Monitoring, Safety. Vaccination

Dated: June 20, 2023

Xavier Becerra,
Secretary,
Department of Health and Human Services.

Accordingly, the final rule amending 45 CFR part 1302, which was published at 86 FR 68052, is adopted as final with the following changes:

PART 1302—PROGRAM OPERATIONS

1. The authority citation for part 1302 continues to read as:

Authority: 42 U.S.C. 9801 *et seq.*

§ 1302.93 [Amended]

2. Amend § 1302.93 by removing paragraphs (a)(1) and (2).

§ 1302.94 [Amended]

3. Amend § 1302.94 by removing paragraphs (a)(1) and (2).

[FR Doc. 2023-13423 Filed: 6/23/2023 8:45 am; Publication Date: 6/26/2023]